A Parallel Randomized Clinical Trial Examining the Return of Urinary Continence After Robot-Assisted Radical Prostatectomy with or without a Small Intestinal Submucosa Bladder Neck Sling

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ABSTRACT

Purpose

Urinary continence is a driver of quality of life after radical prostatectomy. The purpose of this study was to evaluate the impact of a biologic bladder neck sling on postoperative return of urinary continence after robot-assisted radical prostatectomy (RARP).

Materials and Methods

This study compared early continence in patients undergoing RARP with a sling and without a sling in a two group, 1:1, parallel, randomized controlled trial. Patients were blinded to group assignment. The primary outcome was defined as urinary continence (0-1 pads per day) at 1 month postoperative. Inclusion criteria included organ-confined prostate cancer and a prostate-specific antigen <15. Exclusion criteria included any prior surgery on the prostate, history of neurogenic bladder, and history of prior pelvic radiation. A chi-squared test was used for the primary outcome.

Results

A total of 147 patients were randomized (control=74, sling=73), and 92% were available for primary endpoint analysis at 1 month. There were no significant differences in baseline or perioperative data except that operating room time was 20.1 minutes longer for the sling group (*P*=0.04). The continence rate was similar between control and sling groups at both 1 month (47.1% vs. 55.2%, *P*=0.34) and 12 months (86.7% vs. 94.5%, *P*=0.15), respectively. Adverse events were similar between control and sling groups (**10.8%** vs. **13.7%**, *P*=**0.59**).

Conclusions

The application of an absorbable urethral sling at the time of RARP was well tolerated with no increase in obstructive symptoms in this randomized trial. However, the sling failed to show a significant improvement in continence.

INTRODUCTION

Incontinence remains a primary deterrent to the surgical management of prostate cancer, despite technological advancements such as robot-assisted laparoscopic radical prostatectomy (RARP). Researchers have found urinary control to be a driver of quality of life after radical prostatectomy.[1] Late post-prostatectomy continence rates in expert hands are high (76-92%)[2, 3]; however, early continence rates are routinely lower and vary widely (32-84%).[2, 4]

Efforts to improve post-prostatectomy continence include maximizing urethral length,[5] using nerve-sparing techniques,[6] and preserving or recreating urethral support through reconstructive techniques.[2, 7-10] The use of a sling for suspension of the vesicourethral anastomosis at the time of prostatectomy has shown early promise, but has rarely been studied.[11-13] Using an absorbable sling material, such as porcine small intestinal submucosa (SIS), could promote early return of continence. SIS has all cellular components mechanically removed, leaving a biologic scaffold for tissue remodeling. Growth factors, such as fibroblast growth factor-2, are present to support the remodeling process.[14] The purpose of this trial was to prospectively evaluate the impact of an absorbable SIS sling on urinary continence at 1 month and up to 1 year after RARP.

MATERIALS AND METHODS

Study design

This study compared early continence in patients undergoing RARP with or without sling placement in a two-group, 1:1, parallel, superiority, randomized controlled trial. One of three surgeons at a tertiary care institution or a single surgeon at a private hospital performed the procedures. All surgeons were well beyond their learning curve with more than 5 years of experience at the start of the trial. The institutional review board (IRB) at both institutions

approved the study protocol. The Health Insurance Portability and Accountability Act and the Declaration of Helsinki were followed for all study-related procedures and correspondence. Funding was provided by the study sponsor, Cook Incorporated. The ClinicalTrials.gov identifier for the study is NCT00937833.

All patient data were entered by site-specific study coordinators into a secure web-based electronic case report form system. Access to the system required unique login names and passwords. Adverse events were monitored by MED Institute, Inc. and reported to the respective IRB and manufacturer according to normal reporting practice for the participating institutions. For inclusion and exclusion criteria, see Table 1. Randomization was performed by a computerized random number generator and revealed to the surgeon prior to surgery. Patients were blinded to the presence or omission of the sling.

Surgical technique

A robot-assisted transperitoneal radical prostatectomy technique was used as described previously.[15] The decision to proceed with a nerve-sparing procedure was generally made prior to the operative day and based on patient-reported erectile function and tumor pathology results including location of positive biopsy cores. All prostatectomy steps were identical in the control and sling groups. In the sling group, the Cook Biodesign® Surgisis® Urethral Sling was laid posterior to the urethra and bladder neck prior to anastomosis, and one end of the sling was sutured to the ipsilateral Cooper's ligament. After the anastomosis was complete, the other end of the sling was carefully sutured to the periosteum of Cooper's ligament. Care was taken to support the bladder neck but not obstruct it. The sling was tightened until the first small movement of the vesicourethral anastomosis was observed (Figure 1). No additional reconstruction techniques were used in either group.

Outcomes

The primary outcome of the study was continence 1 month after surgery, with continence defined as 0-1 pads per day. Secondary outcomes were time to return of continence, obstructive symptoms related to the sling, and quality of life related to continence and sexual function at 1, 3, 6, and 12 months. Quality of life was measured by the Expanded Prostate Cancer Index Composite (EPIC) questionnaire.[16] The original expanded version (50 questions) was used. Obstructive symptoms were assessed by EPIC question 6d. Pain was assessed on postoperative day 1 by a patient-reported pain score (0-10).

Statistics and sample size

Using retrospective unpublished data, the continence rate at 1 month was hypothesized to be 84% for the treatment group and 69% for the control. Using $\alpha=0.05$ and $\beta=0.2$, the estimated sample size was 251 patients. To account for patients lost to follow-up and study withdrawals, total enrollment was intended to be 280 patients. An interim analysis of the primary outcome was planned when 126 patients had completed 1-month follow-up using an O'Brien-Fleming boundary under futility and efficacy analysis. The interim analysis cutoff for futility was defined as $P \geq 0.367$ and for efficacy was defined as $P \leq 0.006$. The software EAST® 5.5 was used for sample size calculations (Cytel, Inc., Cambridge, Massachusetts, USA). Planned triggers to stop the study included transient urinary retention >20% or permanent urinary retention >10%.

Clinically relevant baseline variables were tabulated. Categorical variables were compared using chi-squared test. Continuous variables were compared using unpaired t-test. Log rank test was used for survival analysis. SAS® 8.2 or higher for Windows® was used for statistical analyses (SAS Institute, Inc., Cary, North Carolina, USA).

RESULTS

Recruitment began in November 2009 and ended in October 2013 after the scheduled interim analysis showed futility of the primary outcome. Overall, 145/147 patients (99%) treated were available for analysis at 1 month, while 117/147 patients (80%) were available through study completion at 12 months (Figure 2). There were no significant differences in baseline characteristics (Table 2). There were no significant differences in perioperative data, except that the operating room time was 20.1 minutes longer for the sling group (P=0.04) (Table 3). Pain scores 1 day postoperative were not significantly different between the control and sling groups (3.4 vs. 3.5, P=0.74) (Table 3).

While not statistically significant, the continence rate (0-1 pads) was higher in the sling group compared to the control group at both 1 month (55.2% vs. 47.1%, P=0.34) and 12 months (94.5% vs. 86.7%, P=0.15) (Table 4, Figure 3). Of those patients who regained continence during the course of the clinical study, the median time to return of continence was 90 days for the control group and 77 days for the sling group; this difference was not statistically different (P=0.61). When continence was defined as zero pads per day, the rate was similar between the sling (13/67) and the control (13/68) groups (p=0.97) at 1 month. EPIC scores were similar between groups for urinary function (Figure 4), sexual function, and obstructive symptoms (Table 4). Finally, the total percentage of patients with adverse events was similar between control and sling groups (10.8% vs. 13.7%, P=0.57), respectively (Table 5). The only bladder neck contracture occurred in the control group. No adverse events were felt to be “probably” or “definitely” related to the sling in the opinion of the principal investigators.

DISCUSSION

Return of continence after RARP remains a primary concern for patients and researchers. In the current randomized study, 92% of randomized patients were available for the 1-month primary outcome assessment and 79% for the final 12-month follow-up. We found a similar improvement in continence rates between 1 and 12 months for the control (47% to 87%) and for the sling group (55% to 95%). Due to futility of the primary endpoint calculated at interim analysis, the study enrollment was stopped at 147 patients (1-month continence rate, p-value=0.34). Importantly, the sling was well-tolerated and total adverse events and obstructive symptoms were not increased by sling placement.

Reports of slings placed at the time of prostatectomy are rare and retrospective in nature, but have shown improvements in continence. In 1997, Jorion[11] harvested rectus muscle fascia at the time of radical retropubic prostatectomy to be used as a sling for the vesicourethral anastomosis. Continence was defined as no protection needed at any time. At 1 month, continence improved for the sling group and approached statistical significance as compared to the control group (60% [18/30] vs. 33% [10/30], *P*=0.069). At 2 months, continence was significantly improved for the sling group as compared to the control group (93% [28/30] vs. 70% [21/30], *P*=0.04). By 9 months, continence was 100% (30/30) for the sling group and 93% (28/30) for the control group. There was a higher rate of nerve sparing in the sling group. The effect of harvesting fascia on the postoperative course was not reported. Early continence rates were higher than in both the current study and what is commonly reported in the literature.[11]

In 2005, Jones et al[12] conducted a small pilot study in which an SIS or a polyglactin sling was placed in 15 patients during radical retropubic prostatectomy. Continence was determined based on clinic notes rather than on a validated instrument or pad weight. Time to continence (no pads needed) was 5.8 weeks for patients in whom slings were placed with no tension and 2.6 weeks

when placed with slight tension. When compared to a control group (n=15) at 3 months, continence was significantly improved for the sling group (47% [7/15] vs. 93% [14/15], *P*=0.01). The authors concluded the sling was safe and that slight tension on the sling may be beneficial. The time to return of continence for the slight tension group was much shorter than the current study (2.6 weeks vs. 11 weeks).[12]

In 2013, Punnen et al[13] reported on the placement of an autologous (vas deferens) retropubic urethral sling at the time of RARP. In total, 153 patients had slings placed; these patients were compared to 78 patients who did not receive slings. The groups were similar, except the sling group was older and underwent fewer nerve-sparing procedures. On multivariate analysis, the time to return of continence (no pads) showed an encouraging hazard ratio of 0.77, with a *P*-value of 0.20 (95 Confidence Interval: 0.52-1.15). The authors reported a selection bias, as those patients with a higher risk of incontinence were more likely to receive a sling. Currently, the authors are conducting a randomized trial to assess the effect of the vas deferens sling on urinary control; study completion is projected for 2017.[17]

One limitation of the current study was a lack of standardization of sling tension. All surgeons attempted to apply the sling to support the bladder neck without obstructing it. The tension required to achieve this objective was left to the discretion of the surgeon without an objective method to measure it. As the reported obstructive symptoms were very similar between groups, it is possible more tension could have been placed on the sling without complication. Future studies should use objective measures of sling tension that allow for testing at multiple tension values. Another limitation is the prolonged accrual of patients, which took four years. However, this is a known difficulty of randomized surgical trials, and the authors do not feel this adversely affected the results. Another limitation is that the surgeons knew the allocation prior to the

prostatectomy, which could have resulted in technique changes. For example, surgeons could have theoretically and subconsciously done a better apical dissection for the sling group resulting in a confounding variable. However, this seems unlikely as the surgeons desired optimal patient outcomes regardless of group allocation and did not have any financial conflicts of interest related to the product. Finally, the surgeons were well beyond their learning curve and at high volume centers, so the results may not be applicable to smaller clinic settings. However, the application of a urethral sling at the time of RARP utilizes basic robotic skills, which do not require advanced training.

CONCLUSIONS

The application of an absorbable vesicourethral sling at the time of robot-assisted laparoscopic radical prostatectomy was well tolerated with no increase in obstructive symptoms in this randomized trial. However, the sling failed to result in a significant improvement in continence. Future studies should assess the effects of differing levels of sling tension on continence and adverse events.

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AUTHOR DISCLOSURE STATEMENT

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Naveen Kella- None

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Michael O Koch- None

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FIGURES

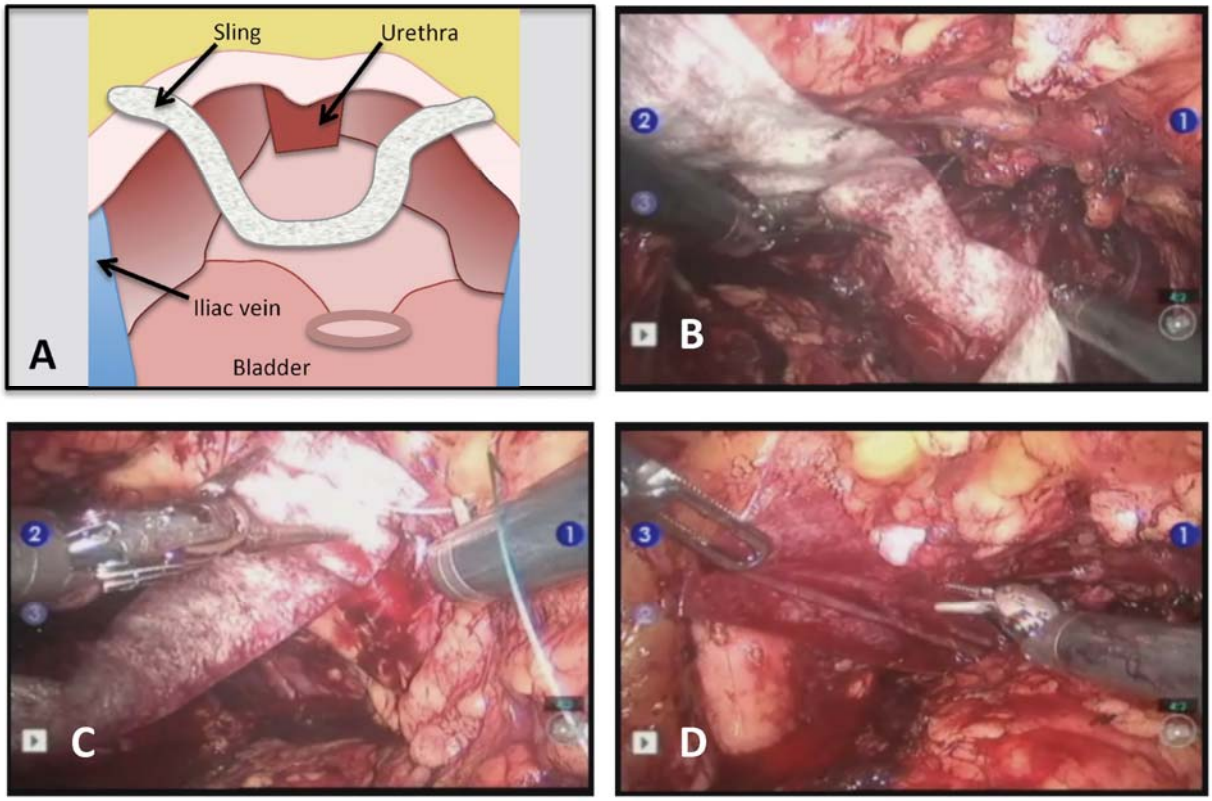

Figure 1: The Cook Biodesign® Surgisis® urethral sling (bioabsorbable) was laid across the pelvic floor in preparation for the vesicourethral anastomosis (A-B). After the anastomosis, the sling was sutured to Cooper's ligament on both sides (C-D) with minimal tension to give support to the anastomosis.

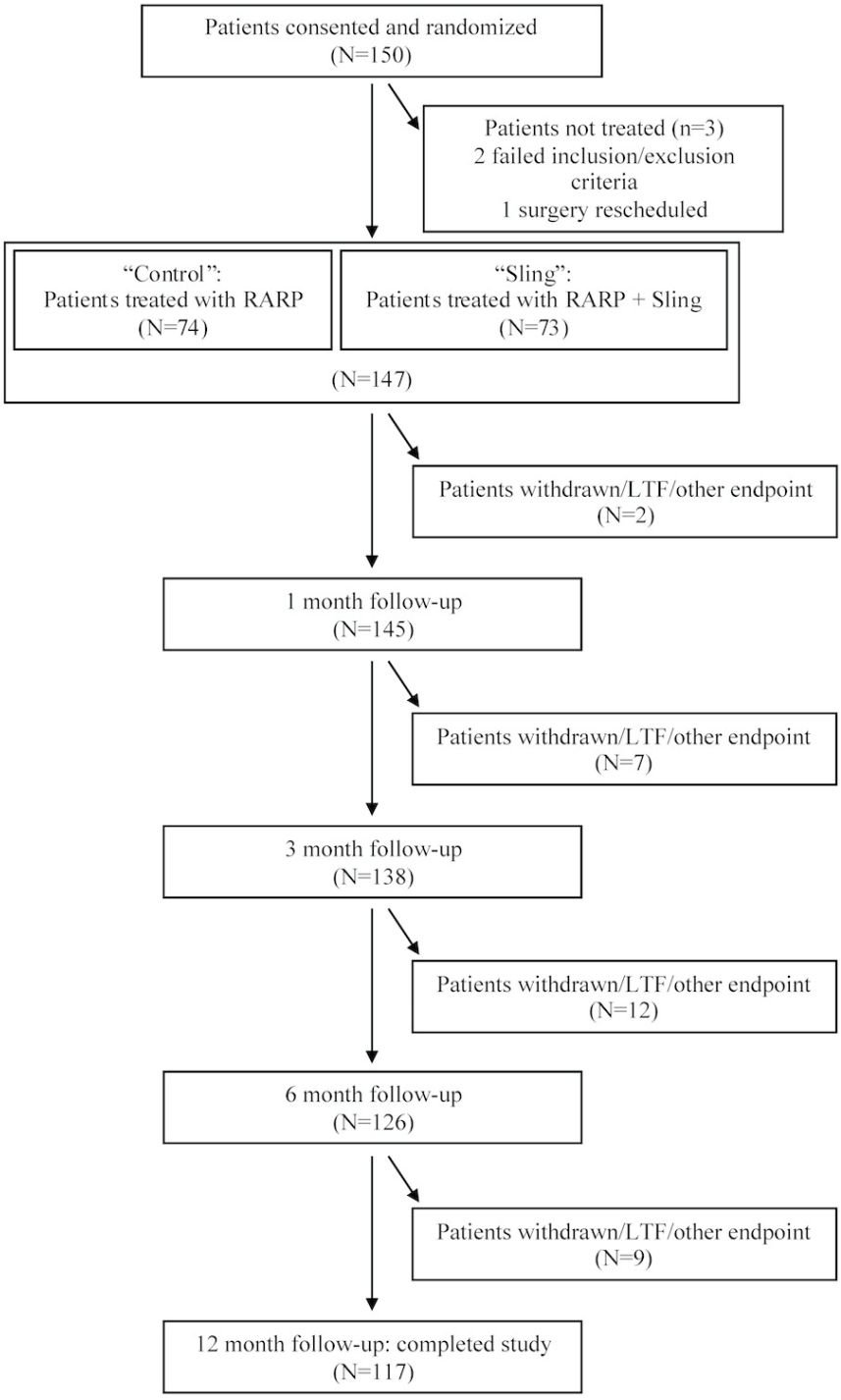

Figure 2: Flowchart for enrollment and follow-up.
RARP = robot-assisted radical prostatectomy; LTF = lost to follow-up

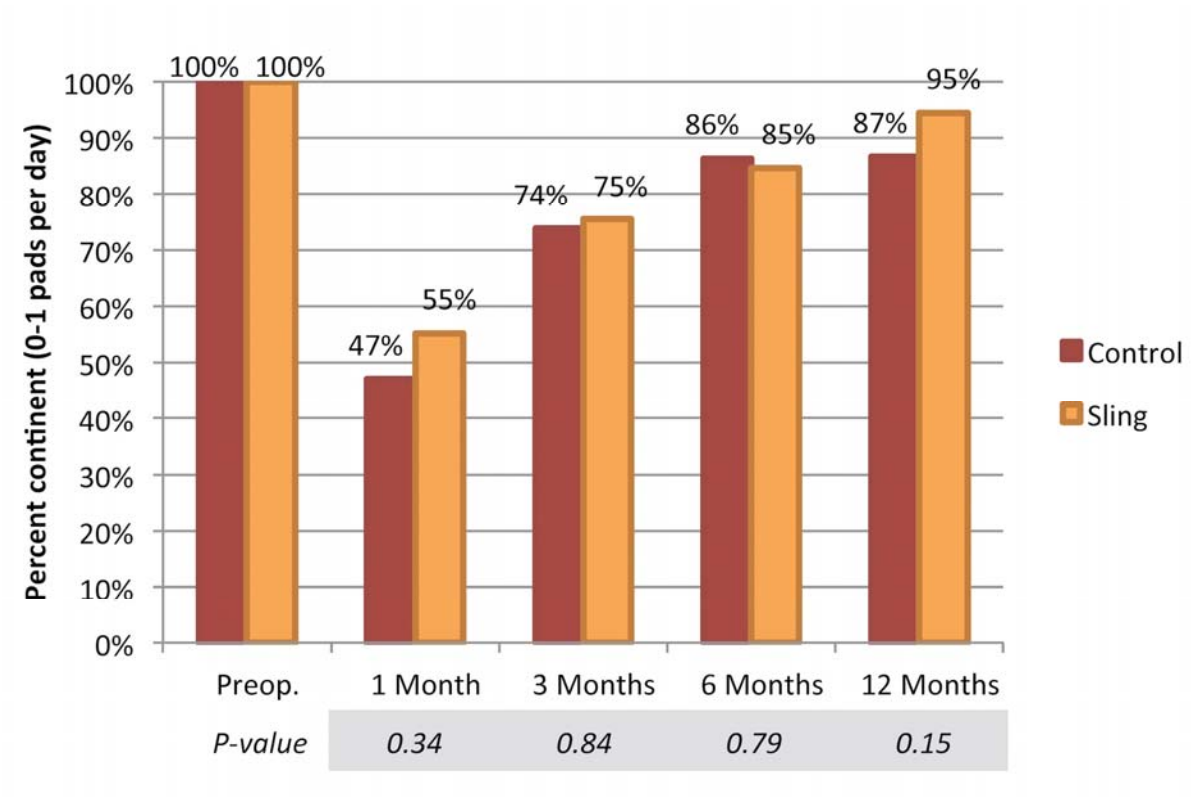

Figure 3: Comparison of continence between the sling and control groups

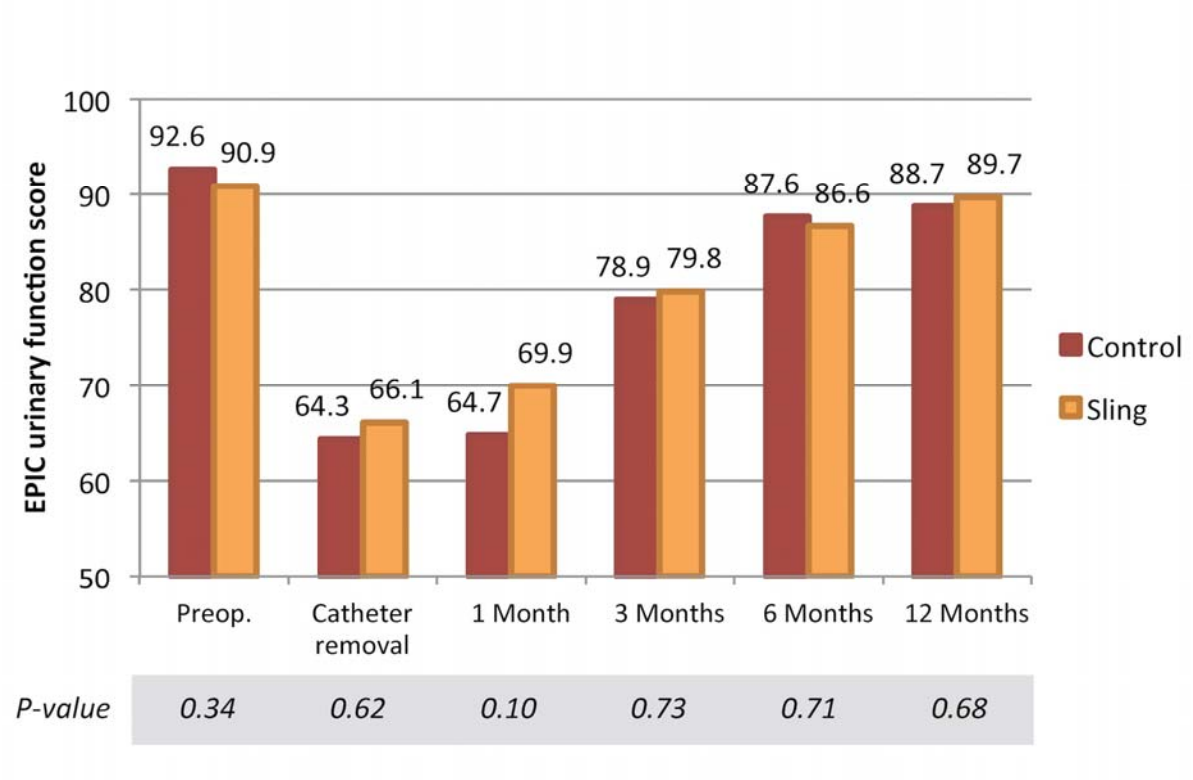

Figure 4: Comparison of EPIC urinary function score for sling and control groups
EPIC = Expanded Prostate Cancer Index Composite

Table 1: Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
1. Organ confined prostate cancer 2. PSA <15 3. Prostate cancer stage <cT3 4. Scheduled for transperitoneal RARP 5. Age ≥18 6. Able to provide written informed consent and HIPAA authorization for release of personal health information	1. Any previous surgery to the prostate 2. Previous incision of urethral stricture or bladder neck contracture 3. Previous diagnosis of urethral stricture, bladder neck contracture, or urinary incontinence 4. Previous diagnosis of atonic or neurogenic bladder 5. Significant preoperative voiding symptoms as defined by an AUA-SS of >19 6. Prior history of radiation to the pelvis 7. Persistent bacteriuria that cannot be cleared 8. Allergies to pig tissue or pig products or religious or cultural objection to the use of pig tissue 9. Prostate is felt to be too large in the opinion of the treating physician

PSA: Prostate-Specific Antigen; RARP: Robot-Assisted Radical Prostatectomy; HIPAA: Health Insurance Portability and Accountability Act; AUA-SS: American Urological Association Symptom Score

Table 2: Baseline characteristics

	Control N=74	Sling N=73	*P*-value
Age, years, Mean ± SD	60.6 ± 7.1	60.9 ± 6.1	0.79
BMI, kg/m^2, Mean ± SD	29.4 ± 4.7	30.0 ± 5.6	0.47
Smoking status, no. (%)			
Non-smoker	45 (60.8%)	43 (58.9%)	0.84
Past smoker	23 (31.1%)	22 (30.1%)	
Current smoker	6 (8.1%)	8 (11.0%)	
Alcohol consumption, no. (%)			
None	34 (45.9%)	34 (46.6%)	0.95
Weekly	25 (33.8%)	23 (31.5%)	
Daily	15 (20.3%)	16 (21.9%)	
Hypertension, no. (%)	31 (41.9%)	38 (52.1%)	0.22
Diabetes, no. (%)	9 (12.2%)	11 (15.1%)	0.61
Urinalysis obtained, no. (%)	73 (98.6%)	71 (97.3%)	0.55
Bacteriuria preoperative, no. (%)	0 (0%)	1 (1.4%)	0.31
PSA, ng/mL, Mean ± SD	6.54 ± 4.01	5.88 ± 2.83	0.25
Gleason score (biopsy), Mean ± SD	6.61 ± 0.74	6.66 ± 0.73	0.68
Clinical stage			**0.27**
T1b	**1 (1.4%)**	**0**	
T1c	**58 (78.4%)**	**61 (83.6%)**	
T2a	**7 (9.5%)**	**8 (11.0%)**	
T2b	**4 (5.4%)**	**4 (5.5%)**	
T2c	**4 (5.4%)**	**0**	

Table 3: Operative and follow-up data

	Control N=74	Sling N=73	*P*-value
Nerve sparing, no. (%)			
Bilateral	57 (77.0%)	53 (72.6%)	0.77
Unilateral	7 (9.5%)	7 (9.6%)	
Non-nerve sparing	10 (13.5%)	13 (17.8%)	
Anastomotic leak intraoperatively, no. (%)	1 (1.4%)	3 (4.1%)	0.3
Leak on postoperative cystogram, leaks/total cystograms performed (%)	**2/38 (5.3%)**	**0/38 (0%)**	**0.15**
Estimated blood loss, mL, Mean ± SD	147.6 ± 83.6	174.7 ± 129.5	0.13
Operating time, minutes, Mean ± SD	174.5 ± 51.8	194.6 ± 65.0	0.04
Intraoperative complications, no. (%)	0 (0%)	0 (0%)	-
Pain score (0-10), postoperative day 1, Mean ± SD	3.4 ± 2.1	3.5 ± 1.9	0.74
Gleason score (pathology report), Mean ± SD	6.97 ± 0.67	7.18 ± 0.95	0.13

Table 4: Primary and secondary outcomes[a]

	Control	**95% C.I.**	Sling	**95% C.I.**	*P*-value
	Continence, n/N (%)				
Preoperative	74/74 (100%)		73/73 (100%)		-
1 Month	32/68 (47.1%)		37/67 (55.2%)		0.34
3 Months	48/65 (73.8%)		49/65 (75.4%)		0.84
6 Months	51/59 (86.4%)		50/59 (84.7%)		0.79
12 Months	52/60 (86.7%)		52/55 (94.5%)		0.15
	EPIC score - urinary function, Mean ± SD (N)				
Preoperative	92.6 ± 9.6 (72)	**90.3, 94.9**	90.9 ± 11.1 (72)	**88.3, 93.5**	0.34
2 days post cath. removal	64.3 ± 21.3 (66)	**59.1, 69.5**	66.1 ± 20.7 (62)	**60.8, 71.4**	0.62
1 Month	64.7 ± 18.2 (65)	**60.2, 69.2**	69.9 ± 18.2 (65)	**65.4, 74.4**	0.10
3 Months	78.9 ± 14.1 (63)	**75.3, 82.5**	79.8 ± 14.8 (64)	**76.1, 83.5**	0.73
6 Months	87.6 ± 12.2 (58)	**84.4, 90.8**	86.6 ± 16 (59)	**82.4, 90.8**	0.71
12 Months	88.7 ± 12.1 (59)	**85.5, 91.9**	89.7 ± 11.9 (54)	**86.5, 92.9**	0.68
	EPIC score - sexual function, Mean ± SD (N)				
Preoperative	61.4 ± 23 (71)	**56.0, 66.8**	57.9 ± 25 (73)	**52.1, 63.7**	0.39
2 days post catheter removal	33.6 ± 25.1 (64)	**27.3, 39.9**	32.9 ± 27 (62)	**26.0, 39.8**	0.88
1 Month	27.7 ± 19.5 (65)	**22.9, 32.5**	26.8 ± 20.3 (65)	**21.8, 31.8**	0.80
3 Months	31.7 ± 19.7 (62)	**26.7, 36.7**	32 ± 23.1 (63)	**26.2, 37.8**	0.94
6 Months	33.8 ± 17.8 (58)	**29.1, 38.5**	34.7 ± 23.3 (58)	**28.6, 40.8**	0.81
12 Months	38.6 ± 20.8 (58)	**33.1, 44.1**	42.5 ± 23 (53)	**36.2, 48.8**	0.35
	EPIC score - obstructive symptoms[b], Mean ± SD (N)				
Preoperative	0.6 ± 0.9 (72)	**0.4, 0.8**	0.8 ± 1.1 (70)	**0.5, 1.1**	0.37
2 days post catheter removal	1.2 ± 1.3 (68)	**0.9, 1.5**	1.2 ± 1.3 (64)	**0.9, 1.5**	0.94
1 Month	1.1 ± 1.2 (65)	**0.8, 1.4**	0.9 ± 1.1 (65)	**0.6, 1.2**	0.32
3 Months	0.5 ± 0.8 (64)	**0.3, 0.7**	0.5 ± 0.9 (64)	**0.3, 0.7**	0.67
6 Months	0.2 ± 0.4 (58)	**0.1, 0.3**	0.3 ± 0.7 (59)	**0.1, 0.5**	0.13
12 Months	0.2 ± 0.5 (60)	**0.1, 0.3**	0.3 ± 0.6 (55)	**0.1, 0.5**	0.83
	AUA-SS, Mean ± SD (N)				
Preoperative	7.4 ± 4.3 (55)	**6.2, 8.6**	8.6 ± 5.6 (55)	**7.1, 10.1**	0.21
2 days post catheter removal	12.3 ± 7.5 (39)	**9.9, 14.7**	12.1 ± 7.6 (35)	**9.5, 14.7**	0.92
1 Month	11.1 ± 6.2 (45)	**9.2, 13.0**	11.0 ± 6.3 (46)	**9.1, 12.9**	0.97
3 Months	8.0 ± 4.2 (39)	**6.6, 9.4**	9.3 ± 5.2 (40)	**7.6, 11.0**	0.21
6 Months	5.9 ± 4.3 (35)	**4.4, 7.4**	7.0 ± 6.5 (33)	**4.7, 9.3**	0.40
12 Months	5.3 ± 4.6 (30)	**3.6, 7.0**	7.0 ± 4.6 (27)	**5.2, 8.8**	0.15

EPIC: Expanded Prostate Cancer Index Composite; AUA-SS: American Urological Association Symptom Score

[a] Not all patients reported all data at each time point. Denominators represent number of patients with data available for analysis.

[b] Taken from EPIC question 6d, "Weak urine stream or incomplete emptying"

Table 5: Adverse events

	Control	Sling
Total adverse events, n/N (%)	8/74 (10.8%)	10/73 (13.7%)
Did event lead to serious adverse event? no. (%)	0/8 (0%)	4/10 (40.0%)
Related to sling? no. (%)		
Not related or unlikely	6/8 (75.0%)	6/10 (60.0%)
Possibly	0 (0%)	4/10 (40.0%)
Probably or definitely	0 (0%)	0/10 (0%)
Description, no. (%)		
UTI	4/8 (50.0%)	3/10 (30.0%)
Pyonephritis	0/8 (0%)	2/10 (20.0%)
Urethral stricture	0/8 (0%)	1/10 (10.0%)
Pelvic abscess	0/8 (0%)	1/10 (10.0%)
Bladder neck contracture, Weck clip erosion	1/8 (12.5%)	0/10 (0%)
Drain erosion into anastomosis	0/8 (0%)	1/10 (10.0%)
Bladder spasm	2/8 (25.0%)	0/10 (0%)
Dysuria	1/8 (12.5%)	0/10 (0%)
Mid ureteral stricture	0/8 (0%)	2/10 (20.0%)